#12 Petition 11-5-01

Atty. Dkt. No. 076518-0146

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrzej Kilian and David Bowtell

Title: VERTEBRATE TELOMERASE GENES AND PROTEINS AND USES THEREOF

Appl. No.: 09/502,498

Filing Date: 02/11/2000

Examiner: M. Walicka

Art Unit: 1652

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Restriction Requirement mailed May 30, 2001. A Petition for a four-month extension of time with the requisite fee, to extend the time to respond to October 30, 2001, is enclosed. Should such a request or any fee be deficient or absent, consider this paragraph such a request and authorization to charge the appropriate fee under 37 C.F.R. §§1.16 to 1.18 to Account No. 19-0741.

Applicants provisionally elect Group II, claims 16-22, drawn to vertebrate telomerase gene, its variants, and fragments, with traverse.

Applicants, of course, reserve the right to file a divisional application covering the subject matter of the non-elected claims. Applicants also elect the species, an amino acid sequence of human telomerase or its variants corresponding to SEQ ID NO: 46. Claims 16-22 of Group II are readable on the elected species.

Introduction

Applicants note that there is a typographical error in the preliminary amendment filed on February 11, 2000 in indicating the claims to be cancelled. On page 6, the list of cancelled claims should include claim 38 instead of claim 28. This is a clear typographical error when viewed in combination with other parts of the preliminary amendment wherein claim 28 has been amended and the remarks stating that claim 38

has been cancelled. See page 7 and 9 of the preliminary amendment. Thus, claims 5, 8, 20, 21, 30, 38 and 45 have been cancelled by the preliminary amendment. Accordingly, claims 1-4, 6, 7, 9-19, 22-29, 31-37, 39-44 and 46-64 are currently pending in the application.

Traversal of Restriction Requirement

The Examiner classified the pending claims into eleven (11) groups. Applicants respectfully traverse the restriction and request the examination of at least Groups I, II, III, IV, V and VI together for the following reasons.

The claims of Groups I, II, III, IV, V and VI are drawn to the inventions as follows:

Group I : DNA, expression vector and transformed host cell to produce recombinantly vertebrate telomerase;

Group II : vertebrate telomerase, its variants and fragments;

Group III : antibody specific for vertebrate telomerase and hybridoma cell for its production;

Group IV : telomorase DNA probe, primers for amplification, and oligonucleotides that hybridize to telomerase gene;

Group V : a method of diagnosing cancer using telomerase cDNA, and a pattern of expression of telomerase RNA; and

Group VI : a method of determining a pattern of expression of telomerase RNA.

For a restriction requirement to be proper, claimed invention must be either independent or distinct, and there must be a serious burden on the Examiner if a restriction is not required. *See* MPEP § 803.

The Examiner asserts that inventions of Groups I, II, III and IV are unrelated because they are independent chemical entities that require an independent search of the patent and non-patent literature. Inventions are unrelated, only "where they are not connected in design, operation, or effect under the disclosure of the particular

application under consideration." MPEP §808.01, at 800-38. Thus, the examiner may only restrict between claims if those claims represent independent inventions, wherein the examiner must establish that there is no disclosed relationship between the restricted claims. Moreover, the particular reasons relied on by the examiner for holding that the inventions as claimed are independent should be concisely stated. A mere conclusory statement is inadequate. MPEP §816.

The examiner fails to provide the particular reasons upon which the independence of these inventions is based. As highlighted above, in the instant case, inventions of Groups I, II, III and IV relate to vertebrate telomerase, as plainly set forth in the claims. The relationship of the inventions in Groups II and III is found from the description of the specification that "[p]eptides may be used as immunogens to raise antibodies, as inhibitors or enhancers of telomerase function, in assays..." In addition, inventions of Groups I and IV are connected in that DNA probes, primers and oligonucleotides claimed in Group IV are simply a part of the telomerase DNA of Group I. Accordingly, these inventions are connected in their operation or effects associated with vertebrate telomerase, and thus the restriction of these groups is improper.

Furthermore, MPEP § 803 recites that if "the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." Applicants contend that this is the case in the present application. When the examiner searches either the DNA or amino acid sequence, a GENEBANK or EMBL search will simultaneously provide the sequence for the corresponding amino acid or DNA sequence. Similarly, when the examiner performs a search for antibodies against the vertebrate telomerase polypeptide, this search will inherently encompass vertebrate telomerases. Thus, there is no undue burden on the examiner to search the DNA sequence encoding vertebrate telomerase, the amino acid sequence which it encodes and the antibody binding to the vertebrate telomerase.

The restriction between claims of Group V and VI is based on the contention that these methods are independent and have different steps and products. However, contrary to the examiner's assertion, the inventions of Groups V and VI are connected

in their operation or effects associated with vertebrate telomerase. Thus, the inventions of Groups V and VI are related.

Where the related inventions are allegedly distinct, the examiner, in order to establish reasons for requiring a restriction, must provide a reasoned basis such as a separate classification, separate status in the art or a different field of search as defined in MPEP §808.02. As the examiner admitted, both Groups V and VI are classified in the same class and subclass, namely, class 435/subclass 6. The examiner has not relied on any evidence establishing a separate status in the art. Accordingly, the examiner has failed to provide evidence in support of a serious burden to examine the claims of Groups V and VI, and therefore the restriction should be withdrawn.

The examiner also has not fully demonstrated that the inventions of Groups V and VI are independent or distinct from Group I or II, and that there is a serious search burden on the examiner. As noted by the examiner, both claims of Group V and VI, which are directed to a process of using either telomerase cDNA or telomerase RNA, are related with claims of Group I as a product and a process of use. The relationship of Group II with Groups V or VI is found in that methods of Groups V and VI involve using a pattern of expression of telomerase RNA, that is, telomerase expressed.

Furthermore, the examiner has not shown that it will be a serious burden to examine the claims of Groups V and VI concurrently with the claims of Group I or Group II. Thus, Applicants believe that searching and examining all of the claims of Groups I, II, V and VI would not place an undue burden on the examiner.

Accordingly, Applicants respectfully request that the examiner reconsider the restriction requirement of Groups I, II, III, IV, V and VI, and examine all of the claims

for the reasons set forth above. Applicants earnestly await receipt of the initial Office Action on the merits.

Respectfully submitted,

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